

Pfizer Inc and BioNTech SE received U.S. regulatory authorization for their COVID-19 vaccine on Friday, making it the first inoculation against the new coronavirus to get a regulatory green light in the United States.

The following is what we know about the race to deliver vaccines to help end the coronavirus pandemic that has killed 1.59 million people worldwide:

Who is furthest along?

U.S. drugmaker Pfizer and German partner BioNTech are the coronavirus vaccine trailblazers.

On Nov. 18, they became the first in the world to release full late-stage trial data. Britain was the first to approve the shot for emergency use on Dec. 3, followed by Canada on Dec. 9 and the U.S. Food and Drug Administration (FDA) on Dec. 11.

The European Medicines Agency (EMA) is due to complete its review of the shot by Dec. 29 and India is accelerating its review.

Who will be next?

U.S. pharmaceutical company Moderna is ahead of the pack at this point. It was next to release full data analysis for a late-stage trial on Nov. 30, with its vaccine showing a 94.1% efficacy rate. FDA advisers are due to review it on Dec. 17 and the EMA will do so by Jan. 12.

Who else is in the running?

Britain's AstraZeneca is seeking approval for its vaccine in Britain after announcing interim late-stage trial data on Nov. 23. It had an average efficacy rate of 70% and as much as 90% for a subgroup of trial participants who got a half dose first, followed by a full dose.

However, it is not clear how the regulator will deal with the different dosages in the efficacy data in its assessment. While India is conducting an accelerated review, it has asked for more data. AstraZeneca is also in discussions with the EMA, which is conducting a rolling review of the vaccine.

U.S. drugmaker Johnson & Johnson plans to deliver trial data this year, or early in 2021, teeing it up for U.S. authorization in February if its shot is effective. It reduced the enrollment target for its clinical trial to 40,000 volunteers from 60,000 on Dec. 9, potentially speeding results which are tied to how quickly participants become infected.

U.S. firm Novavax is running a late-stage trial in Britain with data due in the first quarter of 2021. It expects to start a large-scale trial in the United States this month.

France's Sanofi and Britain's GlaxoSmithKline, however, announced a setback on Dec. 11 in their attempts to develop a vaccine. The drugmakers said it showed an insufficient immune response in older people in mid-stage trials and that they would start a new study in February.

What happens in the trials?

The companies typically test their vaccines against a placebo - typically saline solution - in healthy volunteers to see if the rate of COVID-19 infection among those who got the vaccine is significantly lower than in those who received the dummy shot.

How are volunteers infected?

The trials rely on subjects becoming naturally infected with COVID-19, so how long it takes to generate results largely depends on how pervasive the virus is where trials are being conducted. Each drugmaker has targeted a specific number of infections to trigger a first analysis of their data.



How well are the vaccines supposed to work?

The World Health Organization ideally wants to see at least 70% efficacy. The FDA wants at least 50% – which means there must be at least twice as many infections among volunteers who received a placebo as among those in the vaccine group. The EMA has said it may accept a lower efficacy level.

What about Russia and China?

While Pfizer’s shot was the first to be rolled out following the publication of full Phase III trial data, Russia and China have been inoculating their citizens for months with several different vaccines still undergoing late-stage trials.

Russia said on Nov. 24 that its Sputnik V vaccine, developed by the Gamaleya Institute, was 91.4% effective based on interim late-stage trial results. It started vaccinations in August and has inoculated more than 100,000 people so far.

AstraZeneca said on Dec. 11 that it would test a combination of its vaccine with one of Sputnik V's two components to try to boost the efficacy of the shot it is developing with Oxford University.

China launched an emergency use programme in July aimed at essential workers and others at high risk of infection. It has vaccinated about one million people as of mid-November using at least three shots - two developed by the state-backed China National Biotec Group (CNBG) and one by Sinovac Biotech.

Sinovac said on Nov. 18 that mid-stage trial results showed its CoronaVac shot triggered a quick immune response and interim data from its late stage trial could come this year.

The Butantan Institute, a Brazilian biomedical centre, is producing CoronaVac and aims to make 1 million doses a day ahead of a vaccine campaign to be launched late January.

The United Arab Emirates, meanwhile, said on Dec. 9 that one of the CNBG vaccines was 86% effective based on interim results from a late-stage trial in the Gulf Arab state.

Source: Reuters

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